UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE; ASTRAZENECA LP; KBI INC.; AND KBI-E INC., Plaintiffs and Counterclaim Defendants, v. **HANMI USA, INC., HANMI PHARMACEUTICAL CO., LTD. HANMI FINE CHEMICAL CO., LTD. AND HANMI HOLDINGS CO., LTD.**, Defendants and Counterclaim Plaintiffs.	CASE NO. 3:11-CV-00760-JAP-TJB **DECLARATION OF THE HON. LAWRENCE J. GOFFNEY, JR. ON PTO PRACTICE AND PROCEDURE SUPPORTING THE VALIDITY OF CLAIMS 12, 19 AND 21-22 OF U.S. PATENT NO. 5,877,192 AND SUPPORTING THE VALIDITY OF CLAIMS 1-2, 4, 6 AND 7 OF U.S. PATENT NO. 5,712,504 BASED ON "SOLID STATE"**

I, Lawrence J. Goffney, Jr., declare as follows:

I. BACKGROUND

A. Retention in This Matter

1. Covington & Burling LLP, ("Covington"), counsel for AstraZeneca AB, Aktiebolaget Hässle, AstraZeneca LP, KBI Inc., and KBI-E Inc., (jointly and singularly "AstraZeneca") has retained me on behalf of AstraZeneca (i) to serve as an expert on practice and procedure before the United States Patent and Trademark Office (the "PTO") and (ii) to provide expert opinions in connection with the above-captioned case involving the listed defendants Hanmi USA, Inc., Hanmi Pharmaceutical Co., Ltd., Hanmi Fine Chemical Co., Ltd., and Hanmi Holdings Co., Ltd., (jointly and individually, "Hanmi"), and (iii) if necessary, to testify in the case on matters set forth in this declaration and, to the extent I qualify, in rebuttal to matters brought forth by or on behalf of Hanmi. I submit this declaration pursuant to Federal Rule of Civil Procedure 56 (c) (1) (a). I am being compensated in this matter at my customary billing rate $600/hour, regardless of the outcome, and expenses.

2. Counsel at Covington asked me to set forth my understanding of the practices and procedures before the PTO that applied during the prosecutions of patent application No. 08/256,174 (the "'174 application") that issued as U.S. Patent No. 5,693,818 (the "'818 patent"); patent application No. 08/376,512 (the "'512 application") that issued as U.S. Patent No. 5,714,504 (the "'504 patent"); and patent application No. 08/833,962 (the "'962 application") that issued as U.S. Patent No. 5,877,192 (the "'192 patent"). I have also been asked to respond to assertions about the practices and procedures of the PTO implied or alleged in the "Defendants' Memorandum of Law in Support of Motion for Summary Judgment No. 2: Invalidity of USP 5,877,192 - Claims 12, 19, 21-22," dated October 11, 2011 ("Summary Judgment No. 2") and "Defendants' Memorandum of Law in Support of Motion for Summary

Judgment No. 3: Invalidity of USP 5,714,504 - Claims 1-2, 4, 6 and 7 Based on 'Solid State," dated October 11, 2011 ("Summary Judgment No. 3"). Both Memoranda were in support of Summary Judgment Motions submitted on behalf of Hanmi. Accordingly, I will address my remarks in respect of Hanmi's contentions.

3. Covington asked me to prepare this declaration in light of my knowledge of the practices and procedures of the PTO, particularly with regard to the procedures which patent examiners of the '174 application, the '512 application, and the '962 application were required or authorized to follow in appropriate cases in the normal examination of a patent application as set forth in the Foreword to the M.P.E.P. *See infra,* ¶ 5.

4. I understand that my role in this case is to give expert opinion on patent practice and procedure to help the trier of fact, pursuant to Rule 702 of the Federal Rules of Evidence, understand the prosecution histories of the '174 application, the '512 application, and the '962 application in justifying the claims that issued as, respectively, the '818 patent, the '504 patent, and the '192 patent, and why, in light of PTO practice and procedure, those claims were patentable notwithstanding Hanmi's assertions that these claims should have been rejected on the basis of prior art.

5. I understand that it is improper for a patent practice and procedure expert to advise the judge on the law. I refer in this declaration to statutes and regulations only as those references are used by the Manual of Patent Examining Procedure (the "M.P.E.P."), which provides as follows:

> This Manual is published to provide Patent and Trademark Office patent examiners, applicants, attorneys, agents and representatives of applicants with a reference work on the practices and procedures relative to the prosecution of patent applications before the Patent and Trademark Office. It contains instructions to examiners, as well as other material in the nature of information and interpretation, and outlines the current

> procedures which examiners are required or authorized to follow in appropriate cases in the normal examination of a patent application. The Manual does not have the force of law or the force of the Patent Rules of Practice in Title 37, Code of Federal Regulations.

M.P.E.P. Foreword (5th Ed., Rev. 16, March 1994—7th Ed., July 1998), with insignificant variations.

6. As established in the Foreword, the MPEP is not law. Rather, it sets forth, as administrative policy, procedures that any patent examiner in the PTO is "instructed or authorized to follow in appropriate cases in the normal examination of a patent application." *Supra*, ¶ 5.

7. I also understand that it is improper for a patent practice and procedure expert to instruct the judge on technical matters. Accordingly, I do not intend to have my analyses flawed by overstepping my role as an expert on the practice and procedure of the PTO by opining on technical matters as if I were an expert in the art related to the subject matter of the '818 patent, the '504 patent, and the '192 patent. On technical issues, I defer to AstraZeneca's technical expert, Dr. Stephen Davies, who will provide his opinions about the technical issues concerning the art that was involved in the prosecution of the '174 application, the '512 application, and the '962 application.

B. Qualifications

8. My qualifications for opining about the subject matters of this declaration come from my training and experience as the Assistant Commissioner of Patents and Trademarks of the United States (the "Assistant Commissioner for Patents," the same position is now designated as the "Commissioner for Patents") and Acting Deputy Assistant Secretary of Commerce and Deputy Commissioner of Patents and Trademarks of the United States (the "Deputy Commissioner"), the third and second ranked executive positions in the PTO,

respectively, as well as from my training and experience as a law professor (teaching patent prosecution), as a patent examiner in the PTO, and as a patent prosecution practitioner.

9. I am a patent attorney registered to practice before the PTO. In addition, I am licensed to practice law before the state and federal courts of the State of Michigan and before other federal courts, including the U.S. Court of Appeals for the Federal Circuit. I have been active in the intellectual property bar, having served as a committee chairman and committee member in various intellectual property associations, and I have lectured frequently about patent law, patent policy, and policy and procedures of the PTO to local, state, national, and foreign bar associations, and to scientific and technical communities.

10. Prior to my appointment as Assistant Commissioner for Patents, I was a patent attorney and partner specializing in intellectual property law at the law firm of Dykema Gossett PLLC, with its principal offices located in Detroit, Michigan. I was also resident in its Bloomfield Hills, Michigan, offices.

11. Before I was engaged in private practice in the State of Michigan, I was a patent examiner in the PTO.

12. I have been a law professor on the faculties of the University of Texas and the University of Detroit, as well as a visiting law professor at the University of Wisconsin and a Fellow in Law and the Humanities at Harvard University and the Harvard Law School.

13. I served as the Assistant Commissioner for Patents from 1994 to 1998. As Assistant Commissioner for Patents, I was responsible for all aspects of the functioning of the United States patent organization, including the prosecution of patent applications, the training of patent examiners and the evaluation of the work of all patent examiners. In this regard, my position was the prototype for the position later established as the "Commissioner for Patents." I

visited the European Patent Office and other foreign Patent Offices , studied their examining procedures, and attended Trilateral Meetings with officials of the European Patent Office and the Japanese Patent Office in an ongoing project directed to understanding and improving examination procedures in all Patent Offices . As Assistant Commissioner for Patents and later as Deputy Commissioner of Patents and Trademarks, I was a judge on the Board of Patent Appeals and Interferences, reviewing appeals from final rejections of applications made by patent examiners.

14. Beginning in 1996, I also served as Acting Deputy Assistant Secretary of Commerce and Deputy Commissioner of Patents and Trademarks, during which time I oversaw the policy arm of the PTO, including the Office of Legislative and International Affairs, the Office of Enrollment and Discipline, the Board of Patent Appeals and Interferences, the Trademark Trial and Appeals Board, the Office of Patent Quality Review, the Office of Trademark Quality Review, and for awhile, the Solicitor's Office. I traveled extensively to foreign countries under the auspices of the Department of Commerce and the World Intellectual Property Organization of the United Nations, advising ministers and foreign officials on U.S. intellectual property policy and the Agreement on Trade Related Aspects of Intellectual Property. Also in this role, I reviewed the examination standards set by the PTO, including the performance of patent examiners in their dispositions of patent applications. I authorized regulations for both enrollment and discipline of patent attorneys and agents practicing before the PTO and oversaw and authorized the disciplining of attorneys and agents, such as those who engaged in fraud on the PTO.

15. Following my tenure as Acting Deputy Assistant Secretary of Commerce and Deputy Commissioner of Patents and Trademarks, I joined the law firm of Akin, Gump,

Strauss, Hauer & Feld, L.L.P., as a partner in the firm's intellectual property law practice. I was a partner there until January 2000.

16. Since January 2000 I have been engaged full time in a patent litigation consulting practice and serving as an expert witness on issues involving patent practice and procedure in the PTO. Since January 2000, I have testified in over 75 cases.

17. Attached, as Appendix A, is my curriculum vitae. Appendix A also includes a list of publications and a partial list of papers that I have authored, and lectures that I have given since 1990, as well as a list of cases in which I have testified at trial or in deposition since January 2000.

C. Bases for My Opinions

18. In preparing this declaration, I have considered the documents listed in Appendix B attached to this declaration. In addition, I have reviewed 35 U.S.C. § 1 et seq., the Rules of Practice in Patent Cases (37 CFR § 1.1 *et. seq*. ("Rules 1.1 *et. seq*.")), and versions of the MPEP that were in effect during the prosecutions of the '174 application, the '512 application and the '962 application.

19. I also base my opinions on my experience with PTO practices, procedures, and policies, much of which is set forth in the MPEP, drawing from my background as referred to in preceding paragraphs of this declaration.

II. MY OPINIONS ON HANMI'S ANALYSES BASED ON PTO PRACTICE AND PROCEDURE

A. The '192 Patent

(a) Patent Practice and Procedure Does Not Support Hanmi's Contention that the '192 Patent is not Entitled to the Benefit of the Filing Date of the Swedish Patent Document 9301830; or PCT/SE94/00509; or the '174 Application, all of which have Filing Dates Prior to the Publication Date of WO 94/27988 ("WO '988")

20. To aid the Court in following the temporal relationship between the applications referred to in the first paragraph of the '192 patent, the '504 patent and the '818 patent, I have prepared a figure, entitled "Patents Involved in S/J 2" in Appendix D, that shows when each application that led to these patents was filed and its relative copendency with other applications. Referring to the figure will make clear how the application numbers were connected to respective patent numbers. For example, the '174 application issued as the '818 patent; the '512 application issued as the '504 patent; the '962 application issued as the '192 patent and International Application PCT/SE94/00509 was published as WO 94/27988 ("WO '988").

21. Hanmi asserts that WO '988 is an anticipatory reference against claims 12, 19, 21 and 22 of the '192 patent under 35 U.S.C. § 102(b) because it was published more than one year prior to the filing date of the '962 application that issued as the '192 patent. Hanmi would have the filing date of the '962 application, April 11, 1997, be the effective filing date for claims 12, 19, 21 and 22 of the '192 patent because its claimed priority date depended on the requirements of 35 U.S.C. § 120. According to Hanmi, the '512 application broke the chain of priority from extending back to at least the filing date of the '174 application. *See* Appendix D.

22. In order for the '962 application to be entitled to the benefit of the filing date of the '174 application, 35 U.S.C. § 120 had four requirements for the '512 application and the '174 application, as follows: (1) the '512 application and the '174 application had to disclose the invention of claims 12, 19, 21 and 22 in the manner provided by the first paragraph of 35 U.S.C. § 112; (2) an inventor named in the '512 application and the '174 application had to be the same as an inventor named in the '962 application; (3) the '962

application had to contain, or be amended to contain a "specific reference" to the '512 application and the '174 application; and (4) the '962 application had to have been filed before the patenting or abandonment or termination of proceedings on the '512 application or the '174 application.

23. According to Dr. Davies, the first requirement of 35 U.S.C. § 120 is met as he will opine that the disclosure of the invention of claims 12, 19, 21 and 22 of the '192 patent can be found in the specifications (including the claims) of the applications that issued as the '818 patent and the '504 patent (the '174 application and the '512 application, respectively.)

24. All of the applications share Per Lennart Lindberg, Ph.D., as a named inventor. Therefore, the second requirement of 35 U.S.C. § 120 is also met.

25. The '962 application contains in the first paragraph of the specification a specific reference to the '512 application and the '174 application. The '512 application contains in the first paragraph of the specification a specific reference to the '174 application. Therefore, the third requirement of 35 U.S.C. § 120 is also met.

26. The fourth requirement of 35 U.S.C. § 120, that of copendency, is met by the '962 application because it was copending with the '512 application from April 11, 1997, to February 3, 1998, and the '512 application was copending with the '174 application from January 23, 1995 to December 2, 1997. *See* Appendix D. An interesting aspect of these applications was that the '962 application was also copending with the '174 application from April 11, 1997 to December 2, 1997. Accordingly, it would appear that the '962 application would be entitled to the benefit of the filing date of the '174 application regardless of the '512 application. These two applications contain disclosures of the subject matter of claims 12, 19, 21 and 22 of the '192 patent; they share a named inventor; the '962

application contains a specific reference to the '174 application; and the '174 application and the '962 application were copending.

27. If Dr. Davies is correct in his assessment of the common disclosures of the invention of claims 12, 19, 21 and 22 of the '192 patent as being also present in the '512 application that issued as the '504 patent and the '174 application that issued as the '818 patent, it is my opinion that Hanmi is incorrect in asserting that the effective filing date of the '962 application was the actual filing date of that application. Therefore, Hanmi has no basis for challenging the effective filing date for the '962 application as being June 28, 1994, or that claims 12, 19, 21 and 22 of the '192 patent were not patentable over WO '988 which has a publication date of December 8, 1994 which was well after the effective filing date of the '962 application. Indeed, the '962 application is entitled to the benefit of the May 28, 1993, filing date of the original Swedish application (SE 9301830) because all of the requirements set forth in 35 U.S.C. §§ 119, 365 and 371 were met by the '174 application which issued as the '818 patent.

28. Appendix D provides information regarding: (a) Swedish application SE 9301830; (b) International application PCT/SE4/00509 which was published later as WO '988; (c) the '174 application that issued as the '818 patent; (d) the '512 application that issued as the '504 patent; and (e) the '962 application that issued as the '192 patent. It is readily apparent upon inspection of the figure that each of the three U.S. Patent applications that issued as the '818 patent, the '504 patent and the '192 patent (the '174 application, the '512 application and the '962 application, respectively) were all copending with each other.

(b) Patent Practice and Procedure Does Not Support a Reading That the Claimed Method of Claim 12 Is "Conventional."

29. Hanmi acknowledges that the Summary Of The Invention section of the '192 patent provides that the invention "resides in the discovery that the (-)-enantiomer of omeprazole could achieve certain biological effects not attainable by the prior art racemic form of omeprazole." Summary Judgment No. 2, p. 2. If it is correct to state that the (-)-enantiomer of omeprazole was a novel and non-obvious compound as of May 28, 1993, the priority date of the Swedish priority document and even as of May 27, 1994, the filing date of PCT/SE94/00509, the document that was entered into the national phase in the United States as the '174 application, then the method of claim 12 and dependent claims 19, 21 and 22 was novel and nonobvious because it contained a novel and nonobvious product. This is true notwithstanding that the product was mixed with a pharmaceutically acceptable carrier by conventional means.

(c) Patent Practice and Procedure Does Not Support Hanmi's Contention that Art Discussed in the Background Section of an Application is an Admission of Prior Art

30. As established above, the effective filing date for the '962 application predates the publication of WO '988. Indeed, the publication date of WO '988 necessarily followed its filing date. Therefore, it is unambiguously clear that the publication date of WO '988 did not render it prior art with regard to claims 12, 19, 21 and 22 of the '192 patent. There is no provision that I know of in patent practice and procedure that would have caused a discussion of WO '988 in the Background of the Invention section of the '192 patent to change the effective filing date of claims 12, 19, 21 and 22 of the '192 patent. According to 35 U.S.C. § 120, an application that is entitled to the benefit of an earlier filed application shall have the same effect as to such invention, as though filed on the date of the

prior application. Therefore, it is my opinion that WO '988 is simply not available as prior art against claims 12, 19, 21 and 22 of the '192 patent.

(d) Patent Practice and Procedure Does Not Support Hanmi's Contention that Citation of a Reference on an Information Disclosure Statement is an Admission of Prior Art

31. The MPEP provides the following:

> The filing of an information disclosure statement shall not be construed as a representation that a search has been made. 37 CFR 1.97(g). There is no requirement that an applicant for a patent make a patentability search. Further, the filing of an information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR 1.56(b). 37 CFR 1.97(h). See MPEP § 2129 regarding admissions by applicant.

MPEP 609 (7th Ed. July 1998).

32. MPEP 2001 at that time cited 37 CFR 1.56 for its standard of materiality which provided that material information is information that "establishes by itself, or in combination with other information, a *prima facie* case of unpatentability of a claim." Thus, a *prima facie* case of unpatentability (and therefore a case of unpatentability) cannot be based on a citation of a reference on an IDS as an admission of unpatentability.

33. The PTO has proposed a change in Rule 56(b) defining materiality. The change does not affect PTO practice and procedure with regard to Information Disclosure Statements. Thus the PTO published in the Federal Register/Vol. 76, No. 140/Thursday, July 21, 2011/Proposed Rules as follows:

> While applicants should avoid drafting claims that are unpatentable in the face of the prior art they disclose, the Office will not regard information disclosures as admissions of unpatentability for any claims in the application. *See* § 1.97(h).

34. Reference is made to 37 C.F.R. § 1.97(h) which provides as follows:

> **(h) The filing of an information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b).**

35. Accordingly, it is my opinion that under the present Rule 97(h) (as well as Rule 97(h) as it existed when the '962 application which issued as the '192 patent was being prosecuted) and under proposed changes of rules related to Rule 97(h), a reference submitted on an IDS is not an admission that the reference is prior art against the claims of the that application.

36. I note that on page 18 and in footnote 12 of Hanmi's Summary Judgment No. 2 Hanmi raises an issue of the consideration given by the examiner of an IDS listing WO '988 because Hanmi speculates that the consideration was given on a late date. While I could speculate to the contrary, Hanmi has the burden of proving that the examiner did not do his or her job. The record is clear that WO '988 was cited on an IDS and was considered by the examiner before the '962 application issued as the '192 patent.

B. The '504 Patent

(a) Patent Practice and Procedure Does Not Support Hanmi's Contention That The Phrase "Solid State" Lacks Written Description, Enablement, And Definiteness

37. In Hanmi's Summary Judgment No. 3, Hanmi argues that the term "solid state" in claims 1, 2, 4, 6 and 7 is indefinite, lacks written description, and lacks enablement. Summary Judgment No. 3, p. 2. Examiners were taught the following:

> When not defined by applicant in the specification, the words of a claim must be given their plain meaning. In other words, they must be read as they would be interpreted by those of ordinary skill in the art.

MPEP 2111.01 (6th Ed. July 1996). I understand that Dr. Davies will opine on the meaning of solid state.

38. On January 21, 1997, a personal interview was conducted between the examiner, one of the named inventors, Mr. Drivas (the prosecuting attorney), and Ms. Larsson. During the interview, an agreement was made between the parties to the interview about the following language:

> 1. A pharmaceutical formulation for oral administration of [pure solid state]* (-) enantiomer of omeprazole Na-salt may be allowable after reviewing the data in affidavit form. 2. This is because the prior art teach that (+), (-), (+,-) show same activity in vitro (p. 318, last para. by Erlandsson et al.) and in vivo in Cairns et al. p. 327. 3. The scope of the claim will depend on the data submitted.

* The bracketed words were inserted with a caret.

Since the term "allowable" applies to claims, it follows that the examiner meant that if such language were in a claim, the claim would be allowable.

39. Because examiners are required to avoid piecemeal examination as much as possible, the examiner in the interview recognized that by stating the language was allowable, she was required to have considered all of the issues for allowability including 35 U.S.C. §§ 102, 103 and 112 compliance. *See* MPEP 707.07 (g) (6th Ed. July 1996) ("Major technical rejections on grounds such as lack of proper disclosure, undue breadth, serious indefiniteness . . . should be applied where appropriate even though there may be a seemingly sufficient rejection on the basis of prior art.")

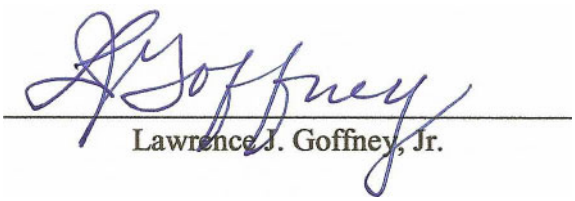
40. Thus, in my opinion, the examiner considered whether the language that had been agreed upon, and which included the words "solid state," was in compliance with 35 U.S.C. § 112's requirements of written description, enablement, and definiteness.

III. CONCLUDING REMARKS

41. For the reasons explained above, I conclude that patent practice and procedure does not support Hanmi's assertions that the '962 application was anticipated by WO '988 because, in compliance with 35 U.S.C. § 120, claims 12, 19, 21 and 22 of the '192 patent, which issued from the '962 application, have an effective filing date prior to the publication date of the WO '988 document. Moreover, I conclude that the applicants did not admit that WO '988 was prior art to the '962 application by way of "conventional" language in claim 12, discussing WO '988 in the Background of the Invention section of the '962 application, or listing WO '988 on the IDS. Furthermore, for reasons explained above, I conclude that patent practice and procedure does not support Hanmi's contention that the phrase "solid state" lacks written description, enablement, and definiteness.

I declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under 18 U.S.C. Section 1001.

Executed on this 2nd day of December 2011.



Lawrence J. Goffney, Jr., consults on intellectual property and serves as an expert witness on patent issues, including proceedings before the United States Patent and Trademark Office (the "USPTO"). Before engaging in his consulting practice in January 2000, he was a partner with Akin, Gump, Strauss, Hauer & Feld, L.L.P., in Washington, where he was a member of the firm's intellectual property practice. He has taught, held appointed office, been a patent examiner and represented Fortune 500 organizations, small businesses and universities in connection with all aspects of intellectual property.

From 1996 until 1998, prior to joining Akin, Gump, Mr. Goffney was the Acting Deputy Assistant Secretary of Commerce and Deputy Commissioner of Patents and Trademarks at the USPTO, a position to which he had been designated by the Secretary of Commerce. He was responsible for overseeing the policy arm of the USPTO, including the Office of Legislative and International Affairs, the Office of Enrollment and Discipline, the Board of Patent Appeals and Interferences, the Trademark Trial and Appeals Board, the respective Offices of Patent and Trademark Quality Review. He traveled extensively to foreign countries under the auspices of the Department of Commerce, the USPTO and the World Intellectual Property Organization of the United Nations, advising foreign officials on U.S. intellectual property policy and Trade Related Aspects of Intellectual Property standards for World Trade Organization members.

In 1994, he had been appointed by the President and confirmed by the Senate to the position of Assistant Commissioner for Patents, in which capacity he ran the entire U.S. official patent process (the "Patent Office") from application to issue. In this capacity, and later as Deputy Commissioner, he attended Trilateral Meetings officials of the European Patent Office and the Japanese Patent Office in an ongoing project by the three major three patent offices of the world directed to understanding each other's examination procedures and operations so that they can cooperate with one another to bring about quality examinations in all of the offices.

Prior to entering government service as a senior official in January, 1994, Mr. Goffney was a partner in the Michigan based law firm of Dykema Gossett, where he practiced in the intellectual property practice group, focusing on patent, trademark and copyright litigation; patent prosecution; and patent, trademark and copyright transactional work. From 1974 until 1983, he was a law professor on the faculties of the University of Texas and the University of Detroit, a visiting professor at the University of Wisconsin and a Harvard Fellow in Law and the Humanities. Mr. Goffney taught courses in patent, trademark and copyright law as well as remedies, antitrust, torts, and creditor's rights. From 1984 until 1986, he examined patents and worked on other projects in the USPTO. From 1986 until his appointment as Assistant Commissioner, he was engaged in private practice.

Mr. Goffney received a B.S. with honors in 1970 from Oakland University. He attended Carnegie Institute of Technology (now Carnegie-Mellon University). He received a J.D. in 1974 from the University of Detroit and an LL.M. in 1974 from Columbia University, where he was a Burton Fellow in Intellectual Property. In 1975, Mr. Goffney received a certificate from the Parker School in Foreign and Comparative Law at Columbia University.

Mr. Goffney is registered to practice before the U.S. Patent and Trademark Office. He is licensed to practice before the state and federal courts in the State of Michigan and before other federal courts, including the U.S. Court of Appeals for the Federal Circuit. He has lectured to local, state, national and foreign bar associations, as well as to scientific and technical audiences.

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SUMMARY

Lawrence ("Larry") Goffney consults on intellectual property and serves as an expert witness on patent issues. He has taught, held appointed office in the United States Department of Commerce and the Patent and Trademark Office, been a patent examiner, and practiced law as a partner in two large law firms where he represented Fortune 500 organizations, small businesses and universities in connection with all aspects of intellectual property.

PROFESSIONAL EXPERIENCE

LGoffney—Alexandria, VA **2000-Present**

- Consultant on practices and procedures in the United States Patent and Trademark Office
- Expert witness on patent issues, including practices and procedures in the United States Patent and Trademark Office

Akin, Gump, Strauss, Hauer & Feld, L.L.P.—Washington, DC **1998-2000**

- Partner in Washington, DC, Office and member of the firm's intellectual property practice.
- Advocacy for firm's clients having intellectual property issues in legislation before Congress
- Practice in client counseling, licensing, and litigation regarding intellectual property issues

Acting Deputy Assistant Secretary of Commerce and—USPTO **1996-1998**
Deputy Commissioner of Patents and Trademarks

- Designated by the Secretary of Commerce
- Responsible for overseeing the policy arm of the USPTO, including the Office of Legislative and International Affairs, the Office of Enrollment and Discipline, the Board of Patent Appeals and Interferences, the Trademark Trial and Appeals Board, the respective Offices of Patent and Trademark Quality Review
- Traveled extensively to foreign countries under the auspices of the Department of Commerce, the USPTO and the World Intellectual Property Organization of the United Nations, advising foreign officials on U.S. intellectual property policy and Trade Related Aspects of Intellectual Property standards for World Trade Organization members
- Attended Diplomatic Conferences at the World Intellectual Property Organization at its headquarters in Geneva, Switzerland
- Attended Trilateral Meetings with officials of the European Patent Office and the Japanese Patent Office

- Still held office as Assistant Commissioner of Patents and Trademarks

Assistant Commissioner for Patents—USPTO **1994-1998**

- Appointed by the President and confirmed by the Senate
- Ran the entire U.S. official patent process (the "Patent Office") from application to issue
- Attended Trilateral Meetings with officials of the European Patent Office and the Japanese Patent Office in an ongoing project by the three major patent offices of the world directed to understanding each other's examination procedures and operations so that they can cooperate with one another to bring about quality examinations in all of the offices

Dykema Gossett—Detroit and Bloomfield Hills, MI **1988-1994**

- Partner and, before that, Associate in the intellectual property practice group of the then largest Michigan based firm with offices nation wide
- Practice focused on extensive patent prosecution; patent, trademark and copyright litigation; and patent, trademark and copyright transactional work
- Served as Partner

Cullen, Sloman, Cantor, Grauer, Scott & Rutherford—Detroit, MI **1986-1988**

- Associate
- Practice focused on extensive patent prosecution; patent, trademark and copyright litigation; and patent, trademark and copyright transactional work.

United States Patent and Trademark Office—Crystal City, VA **1984-1986**

- Examiner in Sheet Feeding and Shock Absorber and Brakes arts

Hoffman & Wheeler, Amarillo, TX **1983-1984**

- Of Counsel

University of Texas School of Law **1979-1983**

- Visiting Professor 1979-1980
- Assistant Professor 1981-1983
- Taught courses in Remedies, Creditors Rights and Bankruptcy, Antitrust, Torts, Intellectual Property, Patent Prosecution, and Legal History
- Served as counsel to University President and as Chairman and member of a number of University committees

University of Detroit School of Law **1978-1979**

1974-1976

Summers 1974-1982

- Assistant Professor and Assistant Dean (resident only 3 years—1974-76 and 1979)

- Taught courses in Remedies, Creditors Rights and Bankruptcy, Antitrust, Torts, Business Torts, Trademarks, Jurisprudence, Intellectual Property, Patent Prosecution, and Legal History
- Served as Chairman and member of a number of committees
- Ran special Summer Institute for beginning law students

University of Wisconsin Law School **1977-1978**

- Visiting Professor
- Taught courses in Remedies and Torts

Harvard University and Harvard University Law School **1976-1977**

- Fellow in Law and the Humanities
- Member of think tank
- Lectured on Slavery issues

EDUCATION

Certificate—Parker School of Foreign and Comparative Law **1975**
Columbia University School of Law, N.Y.

LL.M.—Columbia University School of Law, N.Y. **1974**

- Burton Fellow in Intellectual Property

J.D.—University of Detroit School of Law, Detroit, MI **1973**

- Dean's Award
- Journal of Urban Law (Law Review)
- Alpha Sigma Nu (National Jesuit Honor Society)

B.S.—Oakland University, Rochester, MI **1970**

- Honors in Electrical Engineering
- Tau Beta Pi (National Engineering Honorary)
- Attended Carnegie Institute of Technology before finishing last year at Oakland University.

BAR ADMISSIONS

- State of Michigan
- U.S. District Court for the District of Michigan, Eastern Division
- U.S. District Court of the District of Michigan, Western Division
- U.S. Court of Appeals for the Federal Circuit
- United States Patent and Trademark Office

SELECTED PROFESSIONAL AFFILIATIONS

- American Intellectual Property Association

- American Bar Association, IPL Section
- National Patent Law Association, Intellectual Property Law Section
- Giles Sutherland Rich American Inn of Court

Publications

Digital Tech May Revolutionize Global Commerce, NAT'L L. J., Oct. 25, 1995, at C23.

The New Patent and Trademark Office Paradigm for Design Patents, 24 AM. INTELL. PROP. L. ASS'N Q. J. 317 (1996)

Patent Harmonization Committee Report, AM. INTELL. PROP. L. ASS'N BULL. 486 (May 1995).

WEST'S LEGAL FORMS, PATENTS, TRADEMARKS & COPYRIGHTS (Supp. 1990-93).

Partial List of Presentations and Papers

High Technology Law in the Twenty-First Century: Second Annual High Technology Law Conference, SUFFOLK TRANSNAT'L L. REV. 1 (Winter 1997).

Intellectual Property Rights - Achieving TRIPS Level Protection, APEC INDUSTRIAL PROPERTY RIGHTS SYMPOSIUM (Tokyo, August 1996)(Session 2: Achieving TRIPS Level Protection, "Keynote Address")

New Ideas about Patenting and Regulating Phytotechnical Innovations (with *Robert G. Pinco),* NUTRACON '99 (Las Vegas, July 12-14 1999)

Ethics for Intellectual Property Practitioners, Arlington County Bar Association (Crystal City, VA, April 26 1997)

Japan and the New Asia, Keynote speech for INTELLECTUAL PROPERTY: JAPAN AND THE NEW ASIA (Wash. DC, October 21 1997)

Materials, Processes, and Intellectual Property for the 21st Century, SAMPE'99 (Long Beach, May 25 1999)(Presented to the Society for the Advancement of Material and Process Engineering annual world-wide convention as a part of a Special Keynote Panel)

International Intellectual Property in the 21st Century, 13TH ANNUAL COMPUTER LAW CONFERENCE (1999)(*Sponsored by* The University of Texas School of Law)

Patenting EST's, PATENTING HUMAN GENES: AN INCENTIVE OR IMPEDIMENT TO RESEARCH, AMSIE'97 (Seattle, February 1997) (for the AAAS Annual Meeting and Science Innovation Exposition).

United States Intellectual Property Policy, PROCEEDINGS OF THE THIRD U.S.-KOREA SCIENCE AND TECHNOLOGY FORUM (Copyr. 1996, George Mason University Center for Science, Trade, and Technology Policy)

What's New in Patents? Changes to the U.S. Patent Laws. ASEE ELD 1996 CONFERENCE SESSIONS (Wash. DC 1996)

The State of the United States Patent and Trademark Office, 41ST ANNUAL CONFERENCE ON DEVELOPMENTS IN INTELLECTUAL PROPERTY LAW AT THE JOHN MARSHALL

CASES IN WHICH I HAVE TESTIFIED IN COURT OR BY DEPOSITION SINCE 2000

Since January 1, 2000, I have testified in trial and by deposition in seventy-seven (77) cases. I have testified in trial in fifteen (15) cases:

(1.) *Ziarno v. Red Cross et al., Civil Action No. 99 C 3430 (N.D. Ill.);*

(2.) *Driver ID Inc. v. Triple M Financing and Payment Protection Syste the ms Inc., Case No. 00-70645 (E.D. Mich.);*

(3.) *Tanashin Denki Co., Ltd. v. Thomson Consumer Electronics, Inc., and Thomson Consumer Electronics Canada. Inc., Civil Action No. IP 99-836-C Y/G (S.D. Indiana, Indianapolis Division);*

(4.) *Utah Medical Products, Inc. v. Graphic Controls Corporation, Civ. No. 2:97CV0475 (D. Utah, Central Div.);*

(5.) *Jeneric/Penetron, Inc. v. Dillon Company, Inc., Chemichl AG, and Chemichl, Inc., Civil Action Nos. 3:98-CV-818 (EBB)-LEAD and 3:99-CV-1775 (EBB) (D. Conn.);*

(6.) *Gen-Probe Incorporated v. Vysis, Inc., No. 99-CV-2668H AJB (S.D. Cal.);*

(7.) *In re Omeprazole Litigation, S.D.N.Y., MDL Docket No. 1291 (1999);*

(8.) *Caterpillar Inc. v. Sturman Industries, Inc., Oded E. Sturman, and Carol K. Sturman, C.A. No. 99-CV-1201 (C.D. Ill.);*

(9.) *Fusion Lighting, Inc. v. Westinghouse Electric Corporation, Northrop Grumman Corporation and Edward H. Hooper, Civ. Action No. 209848 (C.C. MD. Mont. County 2000);*

(10.) *Ole K. Nilssen v. Magnetek, Inc., Arbitration No. 51 133 Y 01452 04 (from Case No. 98 C 2229 (N.D.Ill.));*

(11.) *AstraZeneca Pharmaceuticals LP, and AstraZeneca UK Ltd., v. Faulding Pharmaceutical Co., Civil Action Nos. 02 CV 7936 and 03 CV 6487 (WHP) (S.D.N.Y.);*

(12.) *Ole K. Nilssen and Geo Foundation, Inc. v. Osram, Inc., and Osram Products, Inc., Civ. Act. No. 01 CV 3585 (N.D. Ill., 2003);*

(13.) *Heuft Systemtechnik GmbH v. Industrial Dynamics Co., Ltd., Civil Action No. 05CV6299 GPS (JTL) (C.D.Cal.);*

(14.) *In the Matter of: Certain Variable Speed Wind Turbines and Components Thereof, Investigation No. 337-TA-641 (ITC 2009); and*

(15.) *DataTreasury Corporation v. U.S. Bank et al., 2:06-CV-72 DF (E.D. Texas).*

Since January 2000, I have been deposed in seventy-five (75) cases—several times in some of them. I was deposed in 13 of the cases that were cited above as Driver ID v. Triple M Financing and Payment Protection Systems; Tanashin Denki v. Thomson Consumer Electronics, Inc.; Utah Medical Products v. Graphic Controls Corp.; Gen-Probe v. Vysis; In re Omeprazole Litigation, Caterpillar v. Sturman Industries; Fusion Lighting, Inc. v. Westinghouse Electric Corporation; Ole K. Nilssen v. Magnetek, Inc.; AstraZeneca Pharmaceuticals LP and AstraZeneca UK Ltd. v. Faulding Pharmaceutical Co.; Ole K. Nilssen and Geo Foundation, Inc. v. Osram, Inc., and Osram Products, Inc; Heuft Systemtechnik GmbH v. Industrial Dynamics Co., Ltd.; In the Matter of: Certain Variable Speed Wind Turbines and Components Thereof, Investigation, *and* DataTreasury Corporation v. U.S. Bank et al., *and I was deposed in sixty-two (62) other cases, which I cite as follows:*

(1.) *IMT, Inc. and MTI, Inc. v. Haynes & Boone L.L.P., Jeffrey Becker and Timothy Powers, In the County Court at Law Number Two, Dallas, Texas, Cause No. 98-10075-b;*

(2.) *C.R. Bard and Davol, Inc., v. United States Surgical Corporation, Civil Action No. 99-286 (RRM) (D. Del.);*

(3.) *Pechiney Rhenalu v. Alcoa, Inc., Civil Action No. 99-301 (SLR) (D. Del.);*

(4.) *Elonex I.P. Holdings, Ltd.. and Elonex PLC v. Dell Computer Corporation, Viewsonic Corp., Mag Technology USA. Inc., Princeton Graphics Systems, Inc., Micron Electronics, Inc., Mag Technology Co., Ltd., Sony Electronics, Inc., and Capetronic Computer USA (HK), Ltd., Civil Action No. 98-689 (GMS) (D. Del.);*

(5.) *Valeo Electrical Systems, Inc. v. Siemens Automotive Corporation, Civil Action No. 99-CV-40430 (E.D. Mich.);*

(6.) *Don De Cristo Concrete Accessories, Inc. v. American Allsafe Company, Inc., Flex-O-Lite, Inc., and Jackson Products, Inc., d.b.a. Services & Materials Company, SACV00-30 AHS (Eex) (C.D. Cal.);*

(7.) *Rodel, Inc., and Rodel Holdings, Inc. v. Cabot Corporation, C.A. No. 99-256-JJF (D. Del.);*

(8.) *Genzyme Corporation, Genzyme Surgical Products Corporation, Donald P. Elliott, Lynn Halseth, Nicolas F. D'Antonio, and Nicolas J. D'Antonio v. Atrium Medical Corporation, C.A. No. 00-958-RRM (D. Del.);*

(9.) *Leon Stambler v. RSA Security, Inc., Verisign, Inc., First Data Corporation, and Omnisky Corporation, C.A. No. 01-0065-SLR (D. Del.);*

(10.) *In the Matter of Certain Microlithographic Machines and Components Thereof, Investigation No. 337-TA-468 (ITC 2002);*

(11.) *Isis Pharmaceuticals, Inc. v. Sequitur, Inc., Civil Action No. 01 CV 1223, 01 CV 2286, and 02 CV 0842 B (JFS) (S.D. Cal. 2002);*

(12.) *Southwest Die Corporation v. Ontario Die Company Limited, ODC International, Inc. and Ontario Die Company of America, Civil Action No. EP-01-CA-00204-EP (W.D. Tex.);*

(13.) *Tulip computers International, B.V. v. Dell Computer Corporation, Civil Action No. 00-981-RRM (D. Del.);*

(14.) *Isis Pharmeceutical, Inc. v. Sequiture, Inc., Case No. 01 CV 1223 B (S.D.Cal.);*

(15.) *Electronic Trading Systems Corporation v. The New York Mercantile Exchange, Civil Action No. 00-CV-7431-KMW (S.D.N.Y.);*

(16.) *Warner-Lambert Company v. Teva Pharmaceuticals USA, No. 99-922 (DRD) (D.N.J.);*

(17.) *Genentech, Inc., v. Amgen Inc., No. C-96-37WHA (N.D. Cal.);*

(18.) *Wellstat Therapeutics Corp. (f/k/a/ Pro-Neuron, Inc.) v. The Regents of the University of California; Dr. Robert K. Naviaux; Repligen, Inc., and Does 1 through 20, inclusive, No. GIC 769430 (Super. Ct. Cal.)*

(19.) *Leviton Manufacturing, Inc., v. Universal Security Instruments, Inc., 01CV3855 AMD (D.Md.);*

(20.) *Intermark Fabric Corporation v. Microfibres, Inc., Civil Action No. 3-02CV0032-K (D. Conn.);*

(21.) *Donnelly Corporation v. Johnson Controls Technology Company/ Johnson Controls Technology Company and Johnson Controls Interiors, L.L.C. v. Donnelly Corporation, consolidated under Case No. Numeral 1:02-CV-251 (W.D. Mich.);*

(22.) *The Proctor & Gamble Company v. The Coca-Cola Company, Civil Action No. C-01-02-393 (WHR) (S.D. Ohio);*

(23.) *JJK Industries, L.P. v. KPlus, Inc., and Eric A. Klein, Civil Action No. H-02-2259 (S.D. Texas);*

(24.) *MKS Instruments, Inc., and Applied Science and Technology, Inc., v. Advanced Energy Industries, Inc., Civil Action No. 03-03-469-JJF (D.Del.);*

(25.) *Motorola, Inc., v. Analog Devices, Inc., Civil Action No. 1:03-CV-0131 (Clark, J.) (E.D. Texas);*

(26.) *In re Omeprazole II Litigation, MDL Docket No. 1291 (S.D.N.Y. , 1999);*

(27.) *Palomar Medical Technologies, Inc., and The General Hospital Corporation v. Cutera, Inc., Civil Action No. 02-10258-RWZ (D. Mass.);*

(28.) *Cedars-Sinai Medical Center, et al. v. Mitchell, Silberberg & Knupp, LLP, et al., Case No. BC 287823 (Sup. Ct. Cal.) (Lager, J.);*

(29.) *Cephalon, Inc., v. Mylan Pharmaceuticals, Inc., Teva Pharmaceuticals USA, Inc., Barr Laboratories, Inc., and Ranbaxy Laboratories Limited, Civil Action No. 03-CV-1394 (JCL) (D.C.N.J.);*

(30.) *In the Matter of Certain Digital Image Storage and Retrieval Devices, Investigation No. 337-TA-527 (ITC 2004);*

(31.) *Richard J. Ditzik v. ViewSonic Corporation, Samsung Electronics of America, Inc., NEC Mitsubishi Electronics Display of America, Inc, Planar Systems, Inc., Dell, Inc. and CompUSA, Inc., Civil Action Nol 03-74043 (GER) (E.D. Mich.);*

(32.) *Braintree Laboratories, Inc. v. Schwarz Pharma, Inc., Civ. Act. No. 03-477-SLR (D. Del.);*

(33.) *The Regents of the University of California v. Monsanto Company, Case No. C04-00634-PJH (EDL) (N.D. Cal.);*

(34.) *JDS Uniphase Corporation v. Northrop Grumman Corporation, nka Northrop Grumman Systems Corporation and Northrop Grumman Systems Corporation, fka Northrop Grumman Corporation, v. JDS Uniphase Corp., Civil Action No. 03 CV. 332 (GEL) (S.D.N.Y.);*

(35.) *PHT Corporation v. Invivodata, Inc., C.A. No. 04-60 (GMS), and PHT Corporation v. CRF, Inc, C.A. No. 04-61 (GMS) (D.Del);*

(36.) *The Rockefeller University and Chiron Corporation v. Centocor, Inc., and Abbott Laboratories, Civil Action No. 2-04-CV-168-TJW (E.D. Texas);*

(37.) *Xcel Pharmaceuticals, Inc. v. Kali Laboratories, Inc., Civ. Act. No. 2:04-CV-3238 (JCL) (D.N.J.);*

(38.) *In the Matter of Certain Axle Bearing Assemblies, Components Thereof, and Products Containing the Same, Investigation No. 337-TA-554 (ITC);*

(39.) *Gen-Probe Incorporated v. Bayer Healthcare, LLC, and Bayer Corporation, Case No. 04-CV -565LAB (WMC)(S.D. Cal.);*

(40.) *Lucent Technologies Inc. v. Gateway, Inc., Gateway Country Stores LLC, Gateway Companies, Inc., Gateway Manufacturing LLC and Cowabunga Enterprises, Inc., Case No. 02-CV-2060-B (CAB) consolidated with Case No. 03-CV-0699-B (CAB) and Case No. 03-CV-1108-B (CAB);*

(41.) *Caterpillar, Inc., v. Navistar International Transportation Corp., International Truck & Engine Corp., Newstream Enterprises, LLC, Sturman Industries, Inc., and Sturman Engine Systems LLC, Civil Action No. 02 MR 22 (C.C. 10th Jud.Cir. Peoria,Ill.);*

(42.) *Monsanto Company and Monsanto Technology LLC v. Syngenta Seeds, Inc., and Syngenta Biotechnology, Inc., Civil Action 04-305-SLR (D.Del.);*

(43.) *Shuffle Master, Inc., and IGT v. MP Games LLP DB/A MindPlay Games, Robert Mouchou, Alliance Gaming Corp. DB/A Bally Gaming and Systems and Bally Gaming, Inc.,CV-N-04-0407 ECR (RAM) (D. Nev.);*

(44.) *The Board of Regents of the University Of Texas System v. BenQ America Corp., et al., Consolidated Case No. A:05CA (W. D. Texas);*

(45.) *O2 Micro International Ltd. v. Samsung Electronics Co., Ltd. and Samsung Electronics America Inc., Civ. Action No. 2:04-CV-323 (Ward) (E.D. Texas);*

(46.) *The Johns Hopkins University and Arrow International, Inc., v. Datascope Corporation, Civil Action No. 1:05-cv-00759 (WDQ) and 1:06-cv-02711 (WDQ) (D. Md.);*

(47.) *Innovative Solutions and Support, Inc., v. J2, Inc., Joseph Caesar, James Zachary Technologies, Inc., and Kollsman, Inc., Case No.: 05-2665-MI P (W.D. Tennessee);*

(48.) *Murata Manufacturing Co., Ltd., v. Bel Fuse, Inc., Bel Fuse Ltd., Bel Stewart Ltd., and Bel Connector, Inc. d/b/a Stewart Connector and Bel Stewart, Case No. 03C2934 (JBG) (N.D. Ill.);*

(49.) *Walter Kidde Portable Equipment, Inc. v. Universal Security Instruments, Inc., Case No.1:03CV00537 (Judge Bullock) (M.D.N.C.);*

(50.) *Nidec Corporation v. Victor Company of Japan, Ltd., JVC Components (Thailand) Co., Ltd., Agilis Inc., and Agilis Technology Inc., (Defendants), Nidec America Corporation and Nidec Singapore PTE, Ltd., (Additional Defendants on the Counterclaims), Case No.C05 00686 SBA (EMC) (N.D.Cal.);*

(51.) *Howmedica Osteonics Corp. v. Zimmer, Inc., Centerpulse Orthopedics, Inc. (formerly known as Sulzer Orthopedics, Inc.), and Smith & Nephew, Inc., Case No.: 05-897 (WHW) (D. N.J.);*

(52.) *In re Katz Interactive Call Processing Patent Litigation relating to: Ronald A. Katz Technology Licensing L.P. v. Reliant Energy, Inc. et al., 07-cv-2096; Ronald A. Katz Technology Licensing L.P. v. American Airlines et al., 07-cv- 2196; Ronald A. Katz Technology Licensing L.P. v. American Int'l Group, Inc. et al.,07-cv-2 192; Ronald A. Katz Technology Licensing L.P. v. Aetna, Inc. et al., 07-cv-2213; Ronald A. Katz Technology Licensing L.P. v. U.S. Bancorp et al., 07-cv-2360; Ronald A. Katz Technology Licensing L.P. v. Time Warner Cable, Inc. et al., 07-cv-2 134; Ronald A. Katz Technology Licensing L.P. v. American Elec. Power Co., Inc. et al., 07-cv-2257; Ronald A. Katz Technology Licensing L.P. v. General Motors Corp. et al., 07-cv2339; Ronald A. Katz Technology Licensing L.P. v. General Elec. Capital Corp. et al., 07-cv-2336; Ronald A. Katz Technology Licensing, L.P. v. Earthlink, Inc. et al., 07-cv-2325; Ronald A. Katz Technology Licensing L.P. v. Cox Communications, Inc. et al., 07-cv-2299; CVS Caremark Corp. v. Ronald A. Katz Technology Licensing L.P., 07-cv-3 002; Ronald A. Katz Technology Licensing L.P. v. Ahold, USA, Inc. et al, 07-cv 2 101; Ronald A. Katz Technology Licensing L.P. v. DirecTV Group, Inc. et al., 07-cv-2322 RGK (C.D.Cal.);*

(53.) *Medtronic, Inc., Metronic USA, Inc., and Metronic Vascular, Inc., v. AGA Medical Corporation, Case No.C07 00567 SBA (MMC) (N.D.Cal.);*

(54.) *Dow Chemical Canada, Inc., on its own behalf and as assignee of The Dow Chemical Company, v. HRD Corporation (d/b/a Marcus Oil & Chemical), v. Dow Chemical Canada, Inc.,on its own behalf and as assignee of the Dow Chemical Company, and the Dow Chemical Company, C.A. No. 05-023 (JJF) (D. Del.);*

(55.) *Abbott Laboratories and Surmodics, Inc., v. Church & Dwight Co., Inc.,Civil Action No. 07-cv-3428(MFK) (NRL) (N.D. Ill.);*

(56.) *In re Katz Interactive Call Processing Litigation: Track "D" Actions, Case No. 2:07-ML-1816-C-RGK (FFMx) (C.C. Cal.);*

(57.) *Netscape Communications Corp.,v. ValueClick, Inc., Mediaplex, Inc., FastClick, Inc., Commission Cunction,Inc., Mezimedia, Inc. and Web Clients, L.L.C., Civil Action No. 1:09 cv 225 (E.D. Virginia);*

(58.) *Hoffman-La Roche Inc., v. Cobalt Pharmaceuticals Inc., and Cobalt Laboratories, Inc., Civil Action No. 07-4540 (SRC) (MAS) (N.D.N.J.);*

(59.) *DataTreasury Corporation v. Wells Fargo & Company; Wells Fargo Bank, National Association; Bank of America Corporation; Bank of America, National Association; U.S. BanCorp; U.S. Bank, National Association; Wachovia Corporation; Wachovia Bank, National Association; suntrust Banks, Inc.; Suntrust Bank; BB&T Corporation; Branch Banking and Trust Company; BanCorpSouth, Inc.; BanCorpSouth Bank; Compass Bancshares, Inc.; Compass Bank; Cullen/Frost Bankers, Inc.; the Frost National Bank; First Horizon National Corporation; First Tennessee Bank, National Association; HSBC North America Holdings Inc.; HSBC Bank USA, N.A.; Harris BankCorp, Inc.; Harris N.A.; National City Corporation; National City Bank; Zions BanCorporation; Zions First National Bank; Bank of New York Co., Inc.; the Bank of New York; UnionBanCal Corporation; Union Bank of california, National Association; Bank of Tokyo-Mitsubishi UFJ, Ltd.; Citizens Financial group, Inc. City National*

Corporation; City National Bank; Comerica Incorporated; Comerica Bank & Trust, National Association; Deutsche Bank Trust Company Americas; First Citizens BancShares, Inc.; First Citizens Bank & Trust Company; keyCorp; keyBank National Association; Lasalle Bank Corporation; Lasalle Bank NA; M&T Bank Corporation; M&T Bank; the PNC Financial Services group, Inc.; PNC Bank, National Association UBS Americas, Inc.; Small Value Payments Company, LLC; the Clearing House Payments Company, LLC; Magtek, Inc; First Data Corporation; Telecheck Services, In c., Remitco, LLC; and Electronic Data Systems Corp., 2:06-CV-72 DF (E.D. Texas);

(60.) *IMRA America, Inc.,v. IPG Photonics, Case No.: 2:06-15139 (ADT)(E.D. Mich.);*

(61.) *METRIS USA, Inc., METRIS NV, METRIS IPR NV, and 3-D Scanners Ltd., v. Faro Technologies Inc., Civil Action No. 2:06-CV-05818-SDW-MCA (D. Mass.); and*

(62.) *Novartis Pharmaceuticals Corporation v. Mylan Pharmaceuticals Inc. and Mylan Inc., Civil Action No. 2:08-cv-5042-PGS-ES (D. New Jersey)*

APPENDIX B
MATERIALS REVIEWED BY LAWRENCE GOFFNEY, JR. IN PREPARATION FOR FILING EXPERT DECLARATION

No.	Document(s)
1.	Defendants' Memorandum of Law in Support of Motion for Summary Judgment No. 2: Invalidity of USP 5,877,192 - Claims 12, 19, 21-22
2.	Defendants' Memorandum of Law in Support of Motion for Summary Judgment No. 3: Invalidity of USP 5,714,504 - Claims 1-2, 4, 6-7 Based on 'Solid State
3.	Swedish Priority Document SE 9301830-7
4.	WO 94/27988
5.	US Patent 5,693,818 and file history
6.	US Patent 5,714,504 and file history
7.	US Patent 5,877,192 and file history
8.	AstraZeneca's COMPLAINT for Patent Infringement and Certification Pursuant to Local Rule 11.2 against Hanmi USA, Inc., et al., dated February 9, 2011
9.	MPEP 609 (7th Ed. July 1998)
10.	Federal Register/Vol. 76, No. 140/Thursday, July 21, 2011/Proposed Rules
11.	MPEP 2111.01 (6th Ed. July 1996)
12.	MPEP 707.07(g) (6th Ed. July 1996)
13.	35 U.S.C. § 119
14.	35 U.S.C. § 120
15.	35 U.S.C. § 365
16.	35 U.S.C. § 371

APPENDIX C

GENERAL CONSIDERATIONS PERTAINING TO PTO PRACTICE AND PROCEDURE

Structure of the United States PTO

1. This Appendix includes my review of how that part of the PTO that processed patent applications was organized to examine patent applications during the June 28, 1994—March 2, 1999, time frame when the '174 application, the '512 application, and the '962 application were being prosecuted. My review will include the educational requirements for new patent examiners and their training as examiners up to and including their receipt of "signature authority" as primary examiners.

2. In 1993, examiners were organized in Patent Examining Groups ("Groups") generally characterized by broad technology categories in the mechanical, electrical, chemical, design, and some specialized areas, for example, biotechnology and robotics, Each group was managed by a Group Director. By the 1997-March 1999 time frame, many Groups had been consolidated into "super groups" and called "Technical Centers" or "TC's". Many of the TC's were managed by teams of Directors who divided the responsibilities of managing a group among themselves in their management of the "super groups."

3. Each Group or TC was a unit composed of several Art Units of about 7 to 14 patent examiners, who, for the most part, examined patents classified in the same narrowly defined art, although some art units included patent examiners who examined in disparate technologies. Each Art Unit was managed by a Supervisory Primary Examiner or "SPE". An examiner's background and the technology of the patent applications that the examiner was to examine were considerations for examiners' being assigned to a particular art unit. Examiners frequently consulted not only other examiners within their Art Units, but also with examiners in

the more broadly defined groupings of Art Units and throughout the patent organization of the PTO. During the the June 28, 1994—March 2, 1999, time frame when the '174 application, the '512 application, and the '962 application were being prosecuted through the PTO, most of the offices housing examiners in a particular Art Unit were located proximate to a room containing files of issued patents and publications disclosing the technology examined by the examiners in the Art Unit. No such accommodation needed to be made during the September 1998-March 1999 time frame, as most all searches were being conducted from databases that were accessible on a computer in each examiner's office.

4. With only a few exceptions among a corps of a few thousands of examiners, the examiners all had at least a Bachelor's degree or an equivalent amount of semester-hours in a technical field of study. There were however many examiners who had graduate degrees, including Ph.D. s. This was particularly true in the groups that examined pharmaceutical biological technology.

Training and Skill of U.S. Patent Examiners and PTO Resources Available

5. Within each Art Unit, there were three possible rankings of examiners: (1) "Primary Examiner with full signatory authority," an examiner who had the power to dispose of a patent application, either by finally rejecting the application or by allowing the patent to issue; (2) "examiner with partial signatory authority," who had the power to make non-final rejections without having those rejections countersigned by a Primary Examiner; (3) "assistant examiners without any signatory authority," who were required to have all of their rejections and actions countersigned by a Primary Examiner or SPE.

6. All examiners who were not Primary Examiners were generally engaged in a training regimen. Primary Examiners also received training when new rules and procedures

were put into effect in the PTO. All examiners also could and did engage in voluntary training directed to the technology that they examined.

7. Neophyte examiners received classroom training before they actually began their examining duties. This initial training was called “Patent Examiner Initial Training” or “PEIT.” PEIT was conducted as a one to two week overview of patent examining and the MPEP in the Patent Academy, which was an on-campus facility among the numerous buildings occupied by the PTO. This was followed by ongoing on-the-job training under the supervision of Primary Examiners and SPE's and training in the Patent Academy's classrooms.

The Patent Application

8. During the June 28, 1994—March 2, 1999, time frame, a patent application was comprised of several documents, which could have been drafted by the inventor’s patent attorney (or patent agent), but also could have been drafted by the inventor himself or herself or the inventors themselves.

9. Certain parts of the patent application were incorporated into the document that is called a “patent,” including a substantial technical essay generally disclosing the invention and how to make and use it and a listing of claims to the invention. This essay was called the "specification," which comprised a written description of the invention (often including some background information about technology leading to the invention) and the claims. The written description itself was usually divided into several sections that might have been designated respectively as (1) the cross-reference to related applications (if there were any cross-references), (2) the Background of the Invention, (3) the Brief Description of the Drawings (if there were any drawings), (4) the Summary of the Invention, and (5) the Detailed Description of the Invention.

10. The specification was often accompanied by one or more drawings that could be used to illustrate the invention. The drawing or drawings were required in the patent application when necessary for understanding the subject matter to be patented. See M.P.E.P. 608.02 citing 35 U.S.C. § 113. Such drawings are required to follow the standards for drawing set forth by the PTO under 37 CFR §1.84 .

11. The claims, found in the last section of the specification, were as originally filed or amended during prosecution of the application leading to the patent. The claims were statements that defined the invention to which presumably the patent owner would have exclusive rights once the patent issued.

12. While the claims were an important part of the specification because they would serve to define and place limitations on the invention that the owner would have rights to when the patent issued, other parts of the specification (including, a description of at least one embodiment of the invention) were important because these other parts could be used to further define how the invention could be made and used by a person skilled in the technology (or "art") of the subject matter of the claims.

13. The specification, as originally filed or as amended during the application process, as well as any drawings used to illustrate the invention, was incorporated into the patent issuing from the application. Accordingly, the document known as a "patent" contained the text of the "specification" of the patent application (including the claims) and the drawings.

The United States Patenting Process

14. During the June 28, 1994—March 2, 1999, time frame when the '174 application, the '512 application, and the '962 application were being prosecuted, the patenting process for a patent application to be issued as a United States patent was an administrative

process that followed the policies and practices and procedures of the PTO as reflected in the MPEP. Those policies strove to conform to the laws and regulations of 35 U.S.C. § 1 et seq. and 37 CFR § 1.1 et seq. which were incorporated into the MPEP.

15. To obtain a patent during the June 28, 1994—March 2, 1999, time frame when the '174 application, the '512 application, and the '962 applications were pending, an inventor filed a patent application in the PTO, either by mailing the application to the P.O. Box of the PTO and obtaining a filing date on the date that the application was received by the PTO, obtaining a filing date as of the date the application was deposited with the United States Postal Service to be delivered by Express Mail Post Office to Addressee, or obtaining a filing date by personally handing the application to an intake window at the PTO.

16. By the year 1999, electronic copies of an application could have been filed by the applicant over the Internet.

17. Upon receipt in the PTO, an application was referred to a receiving branch that checked to make sure that the application included all the requisite parts. On June 28, 1994, and thereafter during the time frame in which the '174 application, the '512 application and the '962 application were prosecuted through the PTO, paper copies filed in the PTO were copied onto microfilm and the original copies were placed in file folders called "file wrappers" and sent to initial classifiers who classified each application based on its technology. The initial classifiers then sent each file wrapper to an examining Group having technical competence in the subject matter to which the application related. After 1999, many of the applications were scanned into the PTO's electronic copy system and the electronic copies of the applications were received by the initial classifiers and then electronically sent to an examining Group. Within the Group or TC, the application was assigned to an Art Unit based on the application's

particular subject matter. Finally, the SPE for the Art Unit assigned the application or electronic file containing the application to a patent examiner within that Art Unit for consideration.

18. The examiner reviewed the application to learn what the invention was and what was being claimed. In particular, the examiner carefully reviewed the claims, since they determined what exclusive rights would be obtained if a patent were to be issued. The examiner also reviewed other documents included with the application. Often a particular document, known as an Information Disclosure Statement (an "IDS"), was submitted with the application on the filing date or thereafter before the application was examined by the examiner. The IDS was usually accompanied by a form on which United States patent documents identified by patent document numbers (for example, the U.S. Patent No. for a listed United States patent), foreign patent documents (which were identified by foreign document numbers), or other documents (for example, technical articles or excerpts from technical publications). IDSs might have been submitted throughout the prosecution of an application as long as certain rules were followed. *See* MPEP 609 (citing 37 CFR 1.97 and 1.98 ("Rule 97" and "Rule 98," respectively)).

19. After reviewing the application, the examiner conducted a search of the art relating to the claimed invention. The examiner reviewed the PTO patent and literature files, which were organized in a system of classification by technology. During the June 28, 1994—March 2, 1999, time frame when the '174 application, the '512 application and the '962 application were being prosecuted through the PTO, some of the examiners were still searching through patents and literature that were in paper files arranged in flat file drawers called "shoes." A single drawer (called a "shoe" because, as legend would have it, Thomas Jefferson,

the first patent examiner, kept patent applications in his shoe boxes) or several drawers might have housed one or more subclasses within a class of technology related to the invention and analogous technology (called "analogous art") that the examiner determined to be relevant to the invention.

20. There were shoes for foreign patent publications classified under the U.S. classifications, and the Scientific and Technical Information Center ("STIC") at the PTO had a more thorough collection of foreign patent documents, as well as searching services, including the use of the searching capabilities of foreign patent document specialists available to examiners. Patent and patent application documents from the Japanese Patent Office (the "JPO") and the European Patent Office (the "EPO") were housed in the shoes and, the PTO's files contained pre-grant European and Japanese and other foreign patent documents. The PTO, the JPO, and the EPO met annually at Trilateral Meetings to exchange information about search techniques and the availability of documents from the respective offices to examiners of the other respective offices. European patent documents were printed in English as well as French and German. Abstracts of Japanese patent documents were printed in English. STIC had translators on staff or on-call who could translate parts or all of non-English documents.

21. In 1996, personal computers on which searches could be conducted were deployed throughout the examining corps. Paper searches continued throughout the PTO until about 2001.

22. After studying the prior art uncovered during the search or provided by the applicants, the examiner in a particular case sent an Office action to the applicants' agent or attorney. The Office action was a letter stating the PTO's position with respect to the application. In a relatively few cases, a first Office action informed applicants that all claims

were allowed without change and that the application would be issued as a patent. It was much more common, however, for an examiner to reject some or all of an application's claims. A common ground for rejection was the examiner's position that the claims were not patentable over the prior art, which the examiner would have specifically cited.

23. A first rejection therefore induced a response from the applicants upon which the examiner would later comment. In this manner, the examiner and the applicants engaged in a give and take discussion that focused on exactly what was novel and nonobvious and otherwise patentable about the subject matter claimed in the application in light of the prior art.

24. The applicants or the applicants' agent or attorney usually responded to the examiner after the applicants or the applicants' agent or attorney studied the Office action. The applicants' reply was known as a "response", and may have included an "amendment". Accordingly, in a response to an Office action, the applicants might have cancelled or amended the application's claims and included remarks explaining why, in his or her opinion, the claims were patentable or made patentable by the amendment. Sometimes the attorney might have submitted only remarks without amending the claims. The remarks in either case would provide the examiner with further insight into the relationship between the claimed invention and the prior art cited by the examiner in rejecting the claims.

25. Upon receipt of the applicants' response, the examiner reviewed the response and any amendments to the claims. If the examiner then agreed that the claims were patentable, he allowed the application and sent it to another branch to be issued as a patent. If the examiner did not agree with the applicants or the applicants' attorney, he or she again rejected one or more claims through a second Office action sent to the applicants. Even after

this second Office action, which was often deemed "final," the applicants still had the opportunity to convince the examiner that the claims were patentable through the submission of another response containing perhaps another amendment and perhaps an interview with the examiner. If the applicants overcame the examiner's rejection, the examiner would allow the claims and a patent would issue.

26. At any time during the pendency of a patent application, the application could have become abandoned because the applicants failed to respond in a timely fashion to the rejection of claims by the examiner or because the applicants made an express decision in writing to do so. The abandonment of an application, however, did not mean that the invention was abandoned. Depending on the circumstances, an applicant could reapply for a patent on the invention, or could adjust the claims of a related, pending application to prosecute the invention as the invention of the pending application.

27. If the examiner maintained his or her rejection of claims, even while allowing other claims and the applicant did not want to abandon the application (for example, if the applicant did not want to incur the expense of filing another application), the applicant could appeal the examiner's decision to the Board of Patent Appeals and Interferences and, if dissatisfied with the board's holding to the United States Court of Appeals for the Federal Circuit or sue the Commissioner of Patents and Trademarks in the United States District Court for the District of Columbia.

28. Through the above-described exchange of Office actions and responses (which is called "patent prosecution"), the PTO provided a clear record to the public to review and understand the reasons for allowance of patent claims. This exchange permitted the enforcement of the statutory requirements for a patent: that the invention be novel, non-

obvious, and written in such a manner that one skilled in the art could make and use the claimed invention. Each U.S. patent application had to satisfy these standards before it was allowed to issue as a U.S. patent.

Substantive Decisions by Patent Examiners

29. This Appendix continues with the examination of the specification in a patent application during prosecution in the June 28, 1994—December 2, 1997, time frame when the '174 application that issued as the '818 patent was being prosecuted through the PTO and during the January 23, 1995—February 3, 1998, time frame when the '512 application that issued as the '504 patent was being prosecuted and the April 11, 1997—March 2, 1999, time frame when the '962 application that issued as the '192 patent was being prosecuted. Patent examiners were expected to determine whether the specification of each application contained a sufficient written description of the invention to show that the applicant was in possession of the invention at the time the application was filed. See MPEP § 2163. Patent examiners considered whether the specification of the application enabled a person of ordinary skill in the art to make and use the invention. If the specification did not, claims were seen as not supported by the specification and were rejected accordingly. See MPEP § 2164.

30. Examiners were not only to evaluate the specification of a patent application in respect to the written description and enablement requirements, but also in respect to the best mode requirement. See MPEP § 2161. In respect to the best mode requirement, examiners were taught that inventors should not be permitted to disclose second best embodiments of their invention while keeping the best embodiment for themselves. See MPEP § 2165.

31. This Appendix continues with a more specific explication of the examination of the structure of claims during prosecution during the pertinent time frame. An examiner was expected to determine if the claims of an application particularly pointed out and distinctly claimed the subject matter of the invention. This was often called the "definiteness" requirement. The examiner evaluated the definiteness of claim language in light of the prior art, and the disclosure in the specification, as those of ordinary skill in the art to which the invention pertained would have interpreted it. Examiners were instructed to reject indefinite claims.

32. A patent examiner was required to determine whether a claim was anticipated by one or more prior art references and, therefore, not directed to novel subject matter. This required the examiner to determine whether a prior art reference disclosed, expressly or by implication, each and every limitation or step of a particular claim. MPEP § 2131 ("To Anticipate a Claim, the Reference Must Teach Every Element of the Claim.")

33. A patent examiner was also required to determine whether a claim was directed to obvious subject matter. Where no single prior art reference disclosed each and every limitation of the claim, but where, together, a collection of prior art references disclosed each and every limitation of the claim, the examiner would not have considered that the claim was directed to novel subject matter, and if prior to the invention there were a rational basis for one of ordinary skill in the art to combine the references, the examiner would have considered that the claim was directed to obvious subject matter.

THE PROSECUTION HISTORIES OF THE '174 APPLICATION, THE '512 APPLICATION, AND THE '962 APPLICATION

34. The prosecution histories of the '174 application, the '512 application, and the '962 application are not summarized in this Appendix, since the documents in the file

wrappers speak for themselves. Should the Court permit testimony during an oral hearing, I am prepared to provide my opinions about these prosecution histories, from their respective filing dates of the applications to their dates of issue as patents. Accordingly,I am prepared to "walk" through all or parts of the prosecution histories of these applications, explaining PTO terms and identifying PTO procedures and forms.

APPENDIX D

PATENTS INVOLVED IN S/J 2